DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 2, 2014

Beijing Huatai Healthcare Technology Company, LTD.
% Ms. Helen Nan
Wenzhou Cytech Information Service Company, LTD.
Room 302, Number 21 Building, Kaiyu Garden, Xishan South Road
Wenzhou, 325000, Zhejiang
China

Re: K142340
Trade/Device Name: Infrared Therapy System (Model: HW-1000)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 29, 2013
Received: November 5, 2014

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142340

Device Name
Infrared Therapy System (Model: HW-1000)

Indications for Use *(Describe)*
The HW-1000 Infrared Therapy System is intended to emit energy in the near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(k) Summary

(As required by 21 CFR 807.92(a))

5.1 Submitter Information

· Company: Beijing Huatai Healthcare Technology Co.,Ltd.

· Address: Rm.216, No.2 Building, No.18, Qinghe Anningzhuang East Road,Haidian District, Beijing City, 100085, P.R. China

· Phone: 086-10-62931963

· Fax: 086-10-82781040

· Contact: Bingxian Zheng, General Manager

· Date: October 29, 2013.

5.2 Device Information

· Trade/Proprietary Name: Infrared Therapy System;

· Common Name: Infrared Lamp;

· Model: VPT-I;

· Classification: Device Class: 2
Review Panel: Physical Medicine
Name: Lamp, Infrared, Therapeutic Heating
Regulation Number: 21 CFR 890.5500
Product Code: ILY

· Predicate Device: GIGALaser 1801 Submitted by PowerMedic ApS;
K Number: K134017

· Device Description:

The HW-1000 Infrared Therapy System is an effective, drug-free and non-invasive device which can deliver 850-950nm infrared energy through light emitting diodes (LED) mounted in the therapy pads (the same as light panels, but different expressions). Each pad has 66 diodes.

The device consists of mainframe, which contains the user interface panel, the power supply, and the output jack used to connect pad to provide output, and therapeutic pads. When working, the plug of therapeutic pads is connected with the output jack of mainframe and the therapy pads are fixed on the surface of skin directly with matched bandages to provide heating.

· Intended Use:

The HW-1000 Infrared Therapy System is intended to emit energy in the near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.

5.3 Comparison of Required Technology Characteristics

Item	Subject Device	Predicate Device
Intended Use	Intended to emit energy in the near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.	Intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and for the temporary relaxation of muscles.
Design Principle	NIR (near-infrared) Therapy	Same
Energy Source	LED	Same
Skin Contact Mode	Direct Contact	Same
Power Supply	100-240Vac 50-60Hz	Unknown
Device Temperature	40-45℃	Same

Range		
Skin Surface Temperature	40-45℃	Same
Treatment Output	Zero, Moderate, Mild, Strong	6 treatment programs with variable output power levels
Treatment Time	10min±1min, 20min±2min, 30min±3min, 40min±4min	6 treatment programs with variable exposure times
Patient Contact Material	Therapeutic Pad Lower Cover - Medical PC	Unknown
Biocompatibility	Tested according to relevant ISO 10993 Standard	Unknown
Electrical Safety	Tested according to IEC 60601-1	Tested according to EN 60601-1
Electromagnetic Compatibility	Tested according to IEC 60601-1-2	Tested according to EN 60601-1-2

Brief Summary:

First, the subject device shares almost the same intended use with the predicate device, though there is slight difference in the expression of their intended use, that is, the predicate device also boasts visible spectrum which the subject device don't have, such trivial difference will not influence the core usage of the devices, thus will not influencing the substantial equivalence comparison between the two devices.

Secondly, the two devices have similar technological characteristics, for example, they enjoy the same design principle, energy source, skin contact mode, device temperature range and skin surface temperature range. Though they are different in power supply and patient contact material, such differences have been verified by relevant FDA recognized standards - IEC 60601-1, IEC 60601-1-2 and ISO 10993, which supports that the subject device will be as safe for usage as the predicate device. And although they

are not identical in treatment output and time, the effectiveness of the subject device has been evaluated by the following clinical test. Moreover, the subject device share the same therapeutic temperature range with the predicate device which is accepted by FDA, which displays that they will enjoy similar therapeutic effects. All these facts show that the subject device will be as safe and effective as the predicate device, that the two devices are substantial equivalent.

5.4 Discussion of Tests Performed

· Clinical Tests:

The use of light energy to generate heat for therapeutic use has been well documented and is generally accepted alternative treatment modality for the temporary relief of pain and tissue repair.

And in order to evaluate the effectiveness of our subject device, we have sponsored the clinical test with test group receive treatment of the subject device (with power output) and the control group receive treatment of the subject device (without power output), during which no equipment failure or adverse events was discovered and the test result shows that the test group has far better curative effect than the control groups, which further ensures the effectiveness and safety of the subject device. For more details, please refer to Attachment O Clinical Evaluation Report.

· Non-Clinical Tests

The subject device was tested to evaluate its safety according to the following standards:

1) Electrical Safety

AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))

2) Electromagnetic Compatibility

IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General II (ES/EMC))

3) Photobiological Safety

IEC 62471 First edition 2006-07, Photobiological Safety Of Lamps And Lamp Systems. (Radiology)

4) Biocompatibility

AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility) and AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

5) Risk Analysis

ISO 14971 Second Edition 2007-03-01, Medical Devices - Application Of Risk Management To Medical Devices. (General I (QS/RM))

Moreover, the company has performed self-inspection test on the subject device in order to further ensure its safety and effectiveness, especially during which the device temperature and skin surface temperature has been confirmed as 40-45℃ which is accepted by the FDA. More details can be found in Attachment N Performance Self-Inspection Report.

5.5 Conclusion:

First, the subject device enjoys almost the same intended use, which forms the foundation of the substantial equivalence between the two devices. Secondly, the subject device shares similar technological characteristics with the predicate device and the differences in the technological characteristics have been either verified by the above FDA recognized standards or the company's own "Performance Self-Inspection Report", which shows that the subject device will be as safe and effective as the predicate device. Moreover, the effectiveness and safety of the subject device has also be evaluated by appropriate clinical report. All of these facts show that the differences between the two devices will not bring new safety and effectiveness concerns.

As a result, it is reasonable for us to conclude that the subject device is substantially equivalent to the predicate device according to the above analysis.